2/18/99

K983160

510(k) SUMMARY FOR ACTITORIC SOFT (HYDROPHILIC) TORIC CONTACT LENS

K NUMBER: 983160

APPLICANT INFORMATION:

Date Prepared:	January 1999
Company Name:	Hydron Limited
Company Address:	Hawley Lane Farnborough Hants GU14 8EQ United Kingdom
Contact Person:	Julian Holloway Head of Quality Assurance and Regulatory Affairs
Phone No: Fax No:	011 44 1252 554500 011 44 1252 544040

DEVICE INFORMATION:

Regulatory Classification:	Class II – Ophthalmic devices
Trade Name:	ActiToric (ocufilcon A)
Classification Name:	Soft (Hydrophilic) Toric Contact Lens for Daily Wear.

EQUIVALENT DEVICE:

Hydron ActiToric (ocufilcon A) Soft (Hydrophilic) Toric Contact Lens for Daily Wear is equivalent to Specialty UltraVision Specialty T (ocufilcon A) Toric Soft (Hydrophilic) Contact Lens for Daily Wear approved by the FDA under 510(k) application K963764, Jan. 1997.

ActiToric (ocufilcon A) Soft (Hydrophilic) Toric Contact Lens for Daily Wear is substantially equivalent to the indication for use of the Specialty T (ocufilcon A) Soft (Hydrophilic) Toric Contact Lens for Daily Wear marketed for use in the US. This lens is in Group 3 ionic, low water content polymers as established by the FDA and located in the Guidance Document for Daily Wear Contact Lenses, Revised Edition May 1994. The physical, optical, and chemical properties of the ActiToric (ocufilcon A) Soft (Hydrophilic) Toric contact Lens for Daily Wear are equivalent to those of the Specialty T (ocufilcon A) Toric Soft (Hydrophilic) Contact Lens for Daily Wear. The subject device utilises the same formulation, manufacturing and sterilisation processes, packaging, Quality Control/Quality Assurance Procedures and established shelf life as the predicate device, the Specialty UltraVision Specialty T (ocufilcon A) Toric Soft (Hydrophilic) Contact Lens for Daily Wear.

A side by side comparison of the physical, optical and mechanical properties establishes the equivalency of these two contact lens products (see Table 2.1).

Table 2.1. Summary of Properties of ActiToric and the Predicate Device, Specialty T.

Property	ActiToric	Specialty T
Material:		
USAN	ocufilcon A	ocufilcon A
Group	3 (ionic)	3 (ionic)
Monomers	2-HEMA, MA, EGDMA	2-HEMA, MA, EGDMA
Manufacturing:		
Process	Spun-cast	Spun-cast
Diameter (mm)	14.5	14.5
Center Thickness (mm)	0.15	0.15
Base curve (mm)	8.95 (equivalent)	8.90 (equivalent)
Physical Properties:		
Refractive Index	1.43 ± 0.001	1.43 ± 0.001
Water content %	45 ± 0.00	45 ± 0.00
Oxygen Permeability*	$11.9 \pm 1.85 \times 10^{-11}$	$12.2 \pm 1.41 \times 10^{-11}$
Light Transmittance %	98 ± 0.4	99 ± 0.4
Mechanical Properties:		
Modulus (N/mm^2)	0.32 ± 0.045	0.33 ± 0.056
Tensile strength (N/mm^2)	0.32 ± 0.116	0.30 ± 0.010
Elongation at break (%)	208 ± 94	186 ± 89

* measured on single lenses Units: $(cm^2 \times ml\ O_2)/(sec \times ml \times mmHg)$

DESCRIPTION OF THE DEVICE:

The ActiToric soft contact lens is a hemispherical shell manufactured of polymerised material of HEMA and other monomeric ingredients crosslinked with EGDMA and other components which yield the appearance of a lens which is designed to fit over the corneal surface of the eye. This lens is designed with varying base curves which conform to the shape of the radius of the cornea and centre over the apex of the cornea to provide corrective refraction for functional conditions of the eye including myopia (near-sightedness), hyperopia (farsightedness) and astigmatism (multiple foci). The lens provides corrective power which is to correspond to the refractive power of the eye to which it is being treated. The lens has an aspheric base curve that is formed in the free surface during the spinning process. Secondary and tertiary curves as well as bevelled edge configurations are built into the lens for the purpose of aiding in lens centration and comfort. The lens is manufactured by spin casting and has a front toric surface which is determined by the shape of the mould to provide consistent optics. Orientation marks are moulded into the front surface as part of the spin casting process. The lens is a prism ballasted, non-truncated toric, with an inferior slab off to help maintain patient comfort. Axis stabilisation is achieved by the action of the lids on the differential thickness profile (prism) of the lens squeezing the thicker portion of the lens to the bottom.

INDICATIONS FOR USE:

Device Name: Hydron ActiToric (ocufilcon A) Soft (Hydrophilic) Toric Contact Lens for Daily Wear.

The Hydron ActiToric (ocufilcon A) Soft (Hydrophilic) Toric Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.50 diopters.

Eyecare practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning, disinfection and replacement. The lens may be disinfected using either a heat, chemical or hydrogen peroxide disinfection system.

TECHNICAL SUMMARY:

1. Toxicology

   All necessary toxicology studies were undertaken and results were within normal limits.

2. Microbiology

   Relevant test procedures have been undertaken and are included with this 510(k) notification.

3. Compatibility

   Compatibility testing is not required as recommended lens care products have been approved for the same lens material (ocufilcon A).

4. Lens Stability

Lens stability testing indicates that the ActiToric lenses can be stored for a time period of up to 8 years with no adverse effect on the lenses.

5. Clinical

Clinical safety data is not required as the device has the same USAN and method of manufacture as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 1999

Hydron Limited
C/O Mr. J.B. Holloway
Head of Quality and Regulatory Affairs
Hawley Lane
Farnborough
Hampshire GU14 8EQ
United Kingdom

Re: K983160
Trade Name: ActiToric (ocufilcon A) Hydrophilic Toric Contact Lens for Daily Wear
Regulatory Class: II
Product Code: LPN
Dated: January 8, 1999
Received: January 11, 1999

Dear Mr. Holloway:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 983160

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Karen Watanabe

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K983160

(Optional Format 3-10-98)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use___

(Optional Format 1-2-96)